

## **REMARKS**

### **Claim Amendments**

Applicants have canceled claims 4 and 8, without prejudice.

Applicants have amended claim 1 to delete the expression "or a derivative thereof."

Applicants have amended claim 2 to recite a method comprising the reaction of solasodine with tetra-O-benzoyl- $\alpha$ -D-glucopyranosyl bromide, tetra-O-acetyl- $\alpha$ -D-glucopyranosyl bromide or tetra-O-pivaloyl- $\alpha$ -D-glucopyranosyl bromide. Support for this amendment may be found, *inter alia*, in former claim 4 as originally filed. Applicants have amended claim 3 to recite a method comprising the glycosylation of the diol of formula IIa with tri-O-benzoyl- $\alpha$ -L-rhamnopyranosyl bromide or tri-O-pivaloyl- $\alpha$ -L-rhamnopyranosyl trichloroacetimidate. Support for this amendment may be found, *inter alia*, in former claim 8 as originally filed.

Applicants make these amendments expressly without waiver of their right to file for and to obtain claims directed to the canceled or amended subject matter in applications claiming priority and benefit herefrom.

None of these amendments constitutes new matter. They mainly place the recitation of dependent claims into the independent claims. They also place the case in condition for allowance or in better form for appeal. 37 C.F.R. § 1.116. Indeed, the amendments respond to and overcome the specific rejections made in the Final Office Action. Their entry is requested. Upon entry of the amendments, claims 1-3, 5-7, and 9 will be pending in this application.

### **Obviousness-Type Double Patenting**

Claims 1-9 stand provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being allegedly unpatentable over co-pending United

States Application 10/555,038 in view of Cham et al. (U.S. Patent 5,958,770) (Cham) and Schmidt et al. (U.S. Patent 6,242,583) (Schmidt). Applicants request that this rejection be held in abeyance until allowable subject matter is found in the instant application and the '038 application. Applicants will then deal with the obviousness-type double patenting rejection in the appropriate way, i.e., by argument or the filing of the appropriate Terminal Disclaimer.

**Rejection under 35 U.S.C. § 102(b)**

Claim 1 stands rejected under 35 U.S.C. § 102(b) as allegedly anticipated by Cham. The Examiner acknowledges that Cham does not refer to glucose-solasodine conjugates wherein the glucose moiety is substituted by a benzoyl or a pivaloyl group. However, the Examiner contends that claim 1 is not limited to glucose-solasodine conjugates substituted by a benzoyl or a pivaloyl group, but also encompasses derivatives such as those allegedly referred to by Cham.

Without conceding the correctness of this rejection, Applicants have amended claim 1 to delete the expression "or a derivative thereof." Amended claim 1 refers only to a glucose-solasodine conjugate wherein the glucose moiety is substituted by a benzoyl or a pivaloyl group. Accordingly, claim 1 is not anticipated by Cham. Applicants request reconsideration and withdrawal of this rejection.

**Rejections under 35 U.S.C. § 103(a)**

Claim 1 stands rejected under 35 U.S.C. § 103(a) as allegedly obvious over Cham in view of Schmidt. The Examiner contends that Cham refers to glucose conjugates of solasodine wherein the hydroxyl groups are substituted by acetyl groups, and that Schmidt teaches the conventional use of acetyl, benzoyl, and pivaloyl groups in sugar synthesis. The Examiner

synthesis. The Examiner concludes that one of ordinary skill at the time the invention was made would have been motivated to use the method allegedly referred to in Holick and the protecting groups allegedly referred to in Schmidt to prepare the compounds allegedly referred to in Cham. Applicants traverse.

As described above, the compounds of the claimed invention are **not** obvious over Cham in view of Schmidt. Holick does not overcome the deficiencies of Cham and Schmidt in rendering obvious the compound of the claimed invention. However, without conceding the correctness of this rejection, Applicants have canceled claim 4 and amended claim 2 to recite the reaction of solasodine with tetra-O-benzoyl- $\alpha$ -D-glucopyranosyl bromide, tetra-O-acetyl- $\alpha$ -D-glucopyranosyl bromide or tetra-O-pivaloyl- $\alpha$ -D-glucopyranosyl bromide. Cham, Holick, and Schmidt do not refer to these specific D-glucopyranosyl donors. Accordingly, claim 2 and claims 5-7 depending therefrom are not obvious over Cham in view of Holick and Schmidt.

Claims 3, 8 and 9 stand rejected under 35 U.S.C. § 103(a) as allegedly obvious over Cham in view of Ohira et al. (U.S. Patent 6,084,081) (Ohira). The Examiner states that Cham refers to solamargine and glucose-solasodine conjugates and that glycosylation of a sugar moiety was well known in the art, as referred to by Ohira, at the time the invention was made. The Examiner concludes that the skilled artisan at the time the invention was made would have been motivated to use a method of glycosylation of a sugar moiety, as referred to by Ohira, to glycosylate a glucose-solasodine conjugate, as referred to by Cham, to prepare solamargine, as referred to by Cham. Applicants traverse.

As described above, the compounds of the claimed invention are **not** obvious over Cham, which allegedly refers to compounds that play a role in control of cellular function and does not

concludes that the skilled artisan at the time the invention was made would have been motivated to substitute a benzoyl or pivaloyl group for the acetyl group in the compound referred to in Cham to produce the compound of the claimed invention. Applicants traverse.

Cham allegedly refers to solasonine or solamargine derivatives that play a role in control of cellular function. Cham does not refer to glucose-solasodine conjugates that are advanced intermediates in solamargine or solasonine synthesis. The advanced intermediates of the claimed invention are not synthesized or selected based on their ability to control cellular function. One skilled in the art would not expect that the derivative allegedly referred to in Cham plays a role in solamargine or solasonine synthesis; nor would the skilled worker expect that the intermediates of the claimed invention play a role in control of cellular function. The skilled worker would thus have had no reason to substitute a benzoyl or pivaloyl group for the acetyl group in the compound allegedly referred to in Cham to produce the compound of the claimed invention. The skilled worker would also have no reason to believe that such substitution would be advantageous in solamargine or solasonine synthesis. Accordingly, claim 1 is not obvious over Cham in view of Schmidt.

Claims 2 and 4-7 stand rejected under 35 U.S.C. § 103(a) as allegedly obvious over Cham in view of Holick (U.S. Patent 5,612,317) (Holick) and Schmidt. The Examiner acknowledges that Cham does not disclose a process for preparing glucose conjugates of solasodine by reacting solasodine with a protected glucopyranosyl donor. However, the Examiner contends that Holick refers to a method for glycosylating an analogous steroid derivative by reacting the steroid with a protected sugar donor. The Examiner further contends that Schmidt refers to the use of acetyl, benzoyl, and pivaloyl protecting groups in sugar

refer to glucose-solasodine conjugates that are advanced intermediates in solamargine or solasonine synthesis. Ohira does not overcome the deficiencies of Cham in rendering obvious the methods of the claimed invention. However, without conceding the correctness of this rejection, Applicants have canceled claim 8 and amended claim 3 to recite the specific  $\alpha$ -L-rhamnopyranosyl donors tri-O-benzoyl- $\alpha$ -L-rhamnopyranosyl bromide or tri-O-pivaloyl- $\alpha$ -L-rhamnopyranosyl trichloroacetimidate. Neither Cham nor Ohira refers to these  $\alpha$ -L-rhamnopyranosyl donors. Accordingly, claim 3 and claim 9 depending therefrom are not obvious over Cham in view of Ohira.

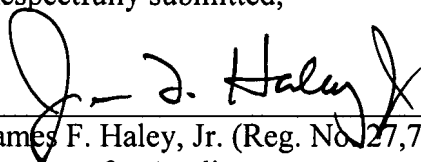
For all of the above reasons, a *prima facie* case of obviousness has not been established. Applicants respectfully request that the Examiner reconsider and withdraw these rejections.

Application No. 10/783,821  
Response dated November 9, 2007  
Responds to May 21, 2007 Final Office Action

**CONCLUSION**

Applicants request favorable consideration and early allowance of the elected claims.

Respectfully submitted,



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